MEDICAL TREATMENT SYSTEM AND METHODS USING A PLURALITY OF FLUID LINES

BACKGROUND

[0001] Peritoneal Dialysis (PD) involves the periodic infusion of sterile aqueous solution (called peritoneal dialysis solution, or dialysate) into the peritoneal cavity of a patient. Diffusion and osmosis exchanges take place between the solution and the bloodstream across the natural body membranes. These exchanges transfer waste products to the dialysate that the kidneys normally excrete. The waste products typically consist of solutes like sodium and chloride ions, and other compounds normally excreted through the kidneys like urea, creatinine, and water. The diffusion of water and solutes across the peritoneal membrane during dialysis is called ultrafiltration.

[0002] A popular form of PD is Automated Peritoneal Dialysis or APD. APD uses a machine, called a cycler, to automatically infuse, dwell, and drain peritoneal dialysis solution to and from the patient's peritoneal cavity. APD is particularly attractive to a PD patient, because it can be performed at home and at night while the patient is asleep. This frees the patient from the day-to-day demands of manually administered peritoneal dialysis (known as CAPD) during his/her waking and working hours.

[0003] The APD sequence or therapy typically lasts for several hours. It often begins with an initial drain phase to empty the peritoneal cavity of spent dialysate. The APD sequence then proceeds through a succession of fill, dwell, and drain phases that follow one after the other. Each sequencing including a fill/dwell/drain is called a cycle.

[0004] During the fill phase, the cycler transfers a predetermined volume of fresh, warmed dialysate into the peritoneal cavity of the patient. The dialysate remains (or "dwells") within the peritoneal cavity for a period of time. This is called the dwell phase. During the drain phase, the cycler removes the spent dialysate from the peritoneal cavity.

[0005] The number of cycles that are required during a given APD session depends upon the total volume of dialysate prescribed for the patient's APD regimen, and is either entered as part of the treatment prescription or calculated by the cycler.

[0006] Conventional peritoneal dialysis solutions typically come in the form of a premixed bag which contains electrolytes and dextrose in concentrations sufficient to generate the necessary osmotic pressure to remove water and solutes from the patient through ultrafiltration. These bags vary in size, but can range up to five or more liters. As several bags of dialysate are generally consumed during a therapy, the patient must maintain a stockpile of a large number of bags in their home to ensure appropriate supplies for continued therapy are available. It is recommended to keep about a month worth or more of supplies on hand. These bags may take up significant space. Additionally, these bags can be heavy making them difficult for patients to move about during set up.

[0007] More recently, there has been a focus on creating new PD solutions which are more physiologically biocompatible. This research is in progress and some solutions which are purported to be more physiologically biocompatible are currently on the market Like conventional solutions, these are provided in bags which contain the full volume of fluid to be used during the therapy. Some of these bags may be compartmented and rely on the user manually manipulate the bag and to mix compartments prior to therapy. This is done since the mixed dialysate is intended for immediate use and does not have a long storage life in mixed state. Such a dialysate solution is evidenced to support better patient outcomes, but may contribute to increased waste, set-up burden, and introduce mixing variability from patient to patient.

[0008] Per the Center for Drug Evaluation and Research of the FDA, "manufacturing a sterile fluid like PD solution is highly specialized and complex, and there are limited numbers of manufacturing lines at each company that are capable of making these solutions." Expansion of production "can take months to years for a firm to complete necessary planning and development to initiate the new production lines successfully." Thus, as APD has become a modality of choice for dialysis patients, production of fluids has, in some instances, been unable to keep pace. It is projected that strong future growth in APD will outpace dialysate production capacity and will likely result in future shortfalls. Currently, the FDA states, "preventing and mitigating shortages of medically necessary drugs, like PD fluid, are top priorities for the FDA".

SUMMARY

[0009] In accordance with an embodiment of the present disclosure cassette based fluid pumping system may comprise a pumping cassette having a first side including number of valve wells and second side having a fluid bus. The first and second side may each be covered by a flexible membrane. The system may further comprise a control surface having a number of valve well control stations actuatable with respect to the flexible membrane covering the first side of the cassette to open and close the valve wells when the cassette is mated against the control surface. The system may further comprise a pressure distribution assembly having a positive and negative pressure source and a number of pneumatic valves. The system may further comprise a controller configured to selectively actuate the number of pneumatic valves to apply pressure against the valve well control stations in a valve pumping sequence until a volume displaced through the fluid bus of the pumping cassette from a source to a destination is within a range of a target volume.

[0010] In some embodiments the destination may be selected from a list consisting of a mixing reservoir in fluid communication with the cassette, a heater bag in fluid communication with the cassette, and a pump chamber disposed within the pumping cassette. In some embodiments, the source may be selected from a list consisting of a pump chamber disposed within the pumping cassette, and a source component in fluid communication with the cassette. In some embodiments, the source may be a source component containing one of component from a list consisting of a buffer solution, an acid solution, a purified water source, and a dialysate concentrate. In some embodiments, each valve pumping sequence may transfer under 150 microliters. In some embodiments, each valve pumping sequence may transfer a nominal volume of 70 microliters. In some embodiments, at least one of the number of valve wells may be a dedicated holding volume valve well. In some embodiments, the pumping cassette may include a pump chamber on the first side of the pumping cassette. The